

**REMARKS**

Claims 9-24 are currently pending in this application. Claims 1-8 were previously canceled without prejudice or disclaimer. Applicant respectfully requests reconsideration of this application in view of the following remarks.

**REJECTION UNDER 35 U.S.C. § 102(b)**

Claims 9-24 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 98/51333 to Deisher et al. ("*Deisher*"). (Office Action at pp. 2-6.) The Office cites *Deisher* for allegedly teaching "methods and compositions useful in treatment of reducing ischemic reperfusion injury and reducing necrotic tissue damage and/or vascular injury resulting from ischemic reperfusion by administration of factor XIII," and contends that "stimulation of the proliferation of new blood vessels in ischemic tissues [as recited in the currently pending claims] will inherently occur after the administration of Factor XIII" in the methods disclosed in *Deisher*. (*Id.* at pp. 2 and 6.) Applicant respectfully traverses.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 8<sup>th</sup> Ed., Aug. 2007 Rev. (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); emphasis added). Applicant submits that *Deisher* cannot anticipate the claimed invention because each and every element as set forth in the claims is not found in that reference.

The currently pending claims recite a method of treating ischemic tissues comprising administering activated Factor XIII. For example, independent claims 9 and 14, from which claims 10-13 and 15-24 depend, recite:

Claim 9. A method of treating ischemic tissues, comprising administering activated Factor XIII and thereby stimulating the perfusion of ischemic tissues.

Claim 14. A method of treating ischemic tissues, comprising administering activated Factor XIII and thereby stimulating the proliferation of new blood vessels in ischemic tissues.

(Claims 9 and 14; emphasis added.) The specification teaches that “Factor XIII is activated in vitro by the addition of thrombin to generate FXIIIa” (page 3) and provides detailed instructions for *in vitro* activation of Factor XIII on pages 3-4. Furthermore, all of Examples 1-4 on pages 4-7 of the specification exemplify the administration of activated Factor XIII.

In contrast, *Deisher* does not teach, either expressly or inherently, the administration of activated Factor XIII for treating ischemic tissues, as required by the currently pending claims. Instead, *Deisher* discloses administration of the proenzyme (*i.e.*, zymogen) forms of Factor XIII, and is notably silent regarding *in vitro* activation of the various native and recombinant Factor XIII preparations that may be administered in the methods disclosed therein. (See, *e.g.*, p. 16, ll. 16-19 and p. 18, ln. 26 through p. 19, ln. 33.) In fact, *Deisher* only discloses *in vivo* activation of Factor XIII during the final stages of blood coagulation. (See, *e.g.*, p. 5, ll. 5-9.) Thus, *Deisher* does not teach the administration of activated Factor XIII for treating ischemic tissues, as required by the currently pending claims.

Since *Deisher* fails to teach each and every element set forth in the claims, *Deisher* cannot anticipate the claimed invention. For at least these reasons, Applicant respectfully requests that the rejection of claims 9-24 under 35 U.S.C. § 102(b) be withdrawn.

### **CONCLUSION**

Applicant respectfully requests that this Response under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 9-24 in condition for allowance. Applicant submits that the foregoing remarks do not raise new issues or necessitate the undertaking of any

additional search of the art by the Office. Therefore, this Response should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Response would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of the Response would place the application in better form for appeal, should the Office continue to dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is patentable over the prior art cited against this application. Applicant therefore requests the entry of this Amendment, reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By: \_\_\_\_\_

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